UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SANOFI-AVENTIS U.S. LLC, Plaintiff, v. NOVO NORDISK INC., Defendant.	Civil Action No. **JURY TRIAL DEMANDED**

COMPLAINT

Plaintiff Sanofi-Aventis U.S. LLC ("Sanofi US" or "Plaintiff"), by its attorneys Ropes & Gray LLP, as and for its complaint herein against defendant Novo Nordisk Inc. ("Defendant"), alleges as follows:

PRELIMINARY STATEMENT

1. This is an action brought by Plaintiff Sanofi US, the manufacturer of the long-acting insulin drugs Lantus and Toujeo, against Defendant Novo Nordisk, the manufacturer of a competing drug Tresiba, arising out of Defendant's false and misleading advertising and promotional campaign, and other unfair competitive practices, intended to persuade consumers, healthcare professionals, and pharmacists to switch from Sanofi US's Lantus and Toujeo products to Defendant's Tresiba product, or to prescribe or recommend Defendant's product instead of Sanofi US's products. More particularly, Defendant is engaged in a nationwide advertising and promotional campaign for Tresiba that prominently features false and misleading claims about the continued availability of Lantus and Toujeo. Defendant's conduct has caused (i) irreparable harm to Sanofi US and the reputation of its products, and will continue to cause such harm unless and until it is enjoined, as well as (ii) monetary injury to

Sanofi US from consumers purchasing Defendant's product rather than Sanofi US's products, or converting from Sanofi US's products to Defendant's product, as a result of Defendant's false and misleading advertising and other wrongful conduct. This injury is compounded each time a consumer fills a prescription for Tresiba as the result of Defendant's wrongful conduct.

2. Accordingly, Sanofi US brings this action seeking injunctive relief and monetary damages for (i) false advertising under Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a); (ii) unfair competition under N.J. Stat. Ann. § 56:4-1 *et seq.*; (iii) unlawful practices under N.J. Stat. Ann. § 56:8-1 *et seq.*; (iv) common law unfair competition, unfair sales practices, and/or deceptive sales practices under New Jersey common law; and (v) product disparagement under New Jersey common law.

PARTIES

3. Plaintiff Sanofi-Aventis U.S. LLC is a Delaware limited liability company and registered New Jersey business entity with a business address of 55 Corporate Drive, Bridgewater, New Jersey 08807.

4. On information and belief, Defendant Novo Nordisk Inc. is a Delaware corporation with a business address of 800 Scudders Mill Road, Plainsboro, New Jersey 08536.

JURISDICTION AND VENUE

5. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338, and 1367, and 15 U.S.C. § 1121.

6. This Court has personal jurisdiction over Defendant because, on information and belief, Defendant is a resident of this State, has engaged in acts or omissions within this State causing injury, has engaged in acts or omissions outside of this State causing injury within this State, and/or has otherwise made or established contacts within this State sufficient to permit the exercise of personal jurisdiction.

7. This judicial district is a proper venue pursuant to 28 U.S.C. § 1391(b)(1) and (2) because Defendant resides in this district and a substantial part of the events or omissions giving rise to Sanofi US's claims occurred in this district.

FACTUAL ALLEGATIONS

8. *Diabetes mellitus*, commonly known as diabetes, is a group of diseases in which the pancreas fails to produce enough insulin (Type 1), or cells fail to properly respond to insulin (Type 2), causing irregular blood sugar levels. About 21 million Americans currently are diagnosed with diabetes. Over time, it leads to serious health complications, including heart disease, blindness, and nerve and kidney damage, and it is the seventh leading cause of death in the United States. Insulin drugs, however, can help to manage the disease, improve blood sugar control, and substantially reduce the risk of associated morbidity and mortality.

9. Sanofi US is the manufacturer of Lantus, a long-acting insulin drug used to treat adults with Type 2 diabetes and adults and pediatric patients (children 6 years and older) with Type 1 diabetes, and Toujeo, a long-acting insulin drug used to treat adults with diabetes. (One unit of Toujeo has the same amount of insulin as one unit of Lantus, but has a smaller injection volume and releases its insulin more gradually.)

10. The United States remains Sanofi US's most important market for both Lantus and Toujeo. Indeed, Lantus is the world's best-selling insulin brand, and both Lantus and Toujeo are of great importance to millions of patients, prescribers, and Sanofi US itself.

11. Defendant is the manufacturer of Tresiba, a long-acting insulin drug that competes with Lantus and Toujeo. The U.S. Food and Drug Administration ("FDA") approved Tresiba to treat adults with diabetes on September 25, 2015, and Novo began commercial distribution of Tresiba on or about January 26, 2016.

12. On or about August 2, 2016, CVS Caremark ("CVS"), the prescription benefit manager for many health insurance plans, stated its intent to remove Sanofi US's Lantus and Toujeo from the CVS Standard Formulary effective January 1, 2017, and to replace those two products with Basaglar, a product manufactured by Eli Lilly and Co. Lantus and Basaglar are both insulin glargine 100 Units/mL products, and the FDA relied, in part, on the agency's finding of safety and effectiveness for Lantus to support its approval of Basaglar.

13. A drug formulary is a list of prescription drugs available to enrollees of a given health insurance plan. A formulary may be "tiered," with drugs on a higher tier (*e.g.*, brand-name drugs) offered at a higher co-pay than drugs on a lower tier (*e.g.*, generics). The CVS Standard Formulary is the formulary used by about half of all CVS-administered health insurance plans. The other half of those plans use custom-negotiated formularies, which vary widely in coverage.

14. CVS's decision to remove Lantus and Toujeo from the 2017 CVS Standard Formulary (the "Standard Formulary") will not preclude the sale of either drug to any consumers covered under any CVS-administered health plan. For the roughly half of consumers covered by plans subject to the Standard Formulary, Sanofi US estimates that about 25-30% belong to plans that will continue to cover those products, but place them on a higher tier. The remaining 70-75% belong to plans that will not cover the products, but the products will remain fully available for those consumers to purchase. Indeed, Sanofi US offers a generous co-pay assistance program to consumers whose plans do not cover those drugs, or whose plans require high out-of-pocket payments for those drugs.

15. Moreover, as noted above, roughly half of all CVS-administered prescription benefit plans do not use the Standard Formulary. Individuals who are covered under those

plans may not be impacted by CVS's decision with respect to Lantus, Toujeo, and Basgalar at all, and may continue to be able to obtain Lantus and Toujeo as before. On information and belief, CVS was careful to direct notices about the change only to those members whose prescription drug plans are subject to the change in coverage status, and not to the many millions of individuals for whom there would be no change.

16. Although the change in the Standard Formulary entailed replacing Lantus and Toujeo with the third-party product Basaglar (which, like Lantus, is insulin glargine), Defendant evidently saw this change as an opportunity to market its competing drug Tresiba (which, unlike Lantus and Basaglar, is insulin degludec). Accordingly, on or about September 2, 2016, Defendant launched a nationwide advertising campaign, which continues to the present time, and which has falsely and misleadingly described the effects of CVS's change. On information and belief, this campaign has included printed materials, emails, online content, and oral statements by marketing representatives, and has been directed at (among others) consumers, prescribing physicians and other health care professionals, and pharmacists.

17. For example, one of Defendant's advertisements, disseminated beginning on or around September 2, 2016, a copy of which is attached hereto as Exhibit A, stated as follows:

Effective 1/1/2017
Tresiba® is Now Preferred (Tier 2) on the CVS Caremark National Drug Formulary
Lantus® and Toujeo® Will Be Blocked
Contact Prescribers to Convert Patients to Tresiba®

18. This advertisement is false and misleading. First, the statement "Lantus® and Toujeo® Will Be Blocked" is literally false, because both drugs will remain covered, albeit at a higher co-pay, for about 25-30% of consumers (a figure equating to millions of consumers) covered by plans subject to the Standard Formulary, and will remain available to the rest of the consumers covered by plans on the Standard Formulary with the co-pay assistance offered by

Sanofi US, or out-of-pocket. Moreover, both drugs will remain available as usual to millions more consumers who are covered under CVS-administered plans that are not subject to the Standard Formulary. This advertisement also is also false and misleading insofar as it suggests that Tresiba (not Basaglar) is the replacement for Lantus and Toujeo on the Standard Formulary, when that is not the case. In addition, this advertisement is false and misleading as CVS does not actually have a formulary named the "CVS Caremark National Drug Formulary," and Defendant's use of the word "National" falsely and misleadingly represents that *all* CVS-administered plans in the United States (rather than just a limited subset) will "block" Lantus and Toujeo.

19. On information and belief, Defendant has heightened the confusion caused by its advertising campaign by indiscriminately disseminating advertising and promotional materials stating that "Lantus® and Toujeo® Will Be Blocked," despite the fact that consumers who are covered under CVS-administered plans that do not use the Standard Formulary are entirely unaffected by CVS's change to that formulary. This sort of scare tactic has no place in the market for drugs for life-threatening conditions.

20. For the past three months, Defendant's advertising campaign also has falsely and misleadingly suggested that a switch from Lantus or Toujeo to Tresiba should take place "today," even though the change in the Standard Formulary will not be effective until January 2017. For example, an advertising piece disseminated to physicians over the past several months, a copy of which is attached as Exhibit B, states as follows:

> Tresiba® is Now Preferred (Tier 2) on the CVS Caremark Standard Formulary
> Effective 1/1/2017 Lantus® and Toujeo® will be Blocked
> Start Your Adult Patients on Tresiba® Today!

21. In addition to these false and misleading claims, on information and belief Defendant has disseminated false and misleading claims regarding the status of Lantus and

Toujeo under at least one state health plan. For example, Defendant has disseminated an advertisement, a copy of which is attached as Exhibit C, stating as follows:

Effective 1/1/2017
Tresiba® is Now Preferred (Tier 2) on North Carolina State Health Plan
Lantus® and Toujeo® will be Blocked.
Start Your Patients on Tresiba® Today!

22. In fact, on information and belief, the North Carolina State Health Plan has not announced, or made, any decision to change the coverage status for Lantus or Toujeo under that plan. Defendants' promotion to the contrary is thus literally false.

23. Defendant's advertising and promotional campaign also may include additional false and misleading advertisements, or other materials or communications, of which Sanofi US presently is unaware.

24. Despite Sanofi US's communications with Defendant in September and October 2016, in which it expressed its serious concern about the false and misleading nature of these advertisements, and repeatedly demanded that Defendant immediately cease disseminating them, to date Defendant has refused to agree to remove them from the marketplace.

25. Defendant's advertising and promotional campaign described above already has caused injury to Sanofi US, including by (i) reducing the number of new prescriptions for Lantus and Toujeo, and (ii) increasing the number of conversions from Lantus and Toujeo to Tresiba, and it is expected to continue to cause such injury in the future unless and until it is enjoined.

26. This harm is likely to be exacerbated by the inherent challenges associated with switching from one insulin drug to another: once a patient is switched, for example, from Lantus or Toujeo to Tresiba, practical barriers (such as the need for training the patient on the use of different injection devices and dosing regimen, and medical supervision or monitoring)

impact the ability to make a subsequent switch. This will lead to further lasting injury to Sanofi US.

27. Defendant's actions complained of herein have damaged Sanofi US in an amount that is not yet determined.

28. As a direct and proximate result of Defendant's actions, Sanofi US also has suffered and is suffering irreparable injury for which there is no adequate remedy at law. Absent injunctive relief, Sanofi US will continue to suffer such injury.

29. Defendant's foregoing acts have occurred in interstate commerce and in a manner affecting interstate commerce. On information and belief, a significant portion of Defendant's foregoing acts took place in, or caused harm in, the state of New Jersey (among other places).

30. On information and belief, Defendant's actions have been willful, deliberate, and in bad faith, or in reckless disregard of, or with callous indifference to, Sanofi US's rights.

COUNT I:
FALSE ADVERTISING
LANHAM ACT, 15 U.S.C. § 1125(A)

31. Sanofi US repeats and incorporates by reference the allegations contained in the foregoing paragraphs 1-30 as if fully set forth herein.

32. Defendant's commercial advertising and promotional claims described above are false and misleading statements of fact, made in interstate commerce, that misrepresent the nature, characteristics, and qualities of Sanofi US's Lantus and Toujeo products, and that both deceive and have the capacity to deceive a substantial segment of relevant consumers and potential consumers for the parties' insulin products.

33. Defendant's deception and intended deception was and is material, in that it was and is likely to influence relevant consumers' purchasing decisions.

34. Defendant's commercial advertising claims have caused and are likely to continue to cause damage to Sanofi US and the public, and, unless restrained, will further damage Sanofi US and the public.

35. Defendant's commercial advertising claims are causing immediate and irreparable competitive and commercial injury to Sanofi US, to its goodwill and reputation, and will continue to cause such injury unless enjoined by this Court.

36. On information and belief, Defendant's acts of false advertising are willful, deliberate, and in bad faith.

37. Sanofi US has no adequate remedy at law.

38. Sanofi US is entitled to injunctive relief and to recover up to three times its actual damages and/or an award of Defendant's profits, as well as costs and Sanofi US's reasonable attorney fees, under 15 U.S.C. §§ 1116-17.

COUNT II:
UNFAIR COMPETITION
N.J. STAT. ANN. § 56:4-1 *ET SEQ.*

39. Sanofi US repeats and incorporates by reference the allegations contained in the foregoing paragraphs 1-38 as if fully set forth herein.

40. The conduct described above and throughout this Complaint violates N.J. Stat. Ann. § 56:4-1 *et seq*.

41. Defendant's commercial advertising and promotional claims described above are false and misleading statements of fact, that misrepresent the nature, characteristics, and qualities of Sanofi US's Lantus and Toujeo products, and that both deceive and have the capacity to deceive a substantial segment of relevant consumers and potential consumers for the parties' insulin products.

42. Defendant's deception and intended deception was and is material, in that it was and is likely to influence relevant consumers' purchasing decisions.

43. Defendant's commercial advertising claims have caused and are likely to continue to cause damage to Sanofi US and the public, and, unless restrained, will further damage Sanofi US and the public.

44. Defendant's commercial advertising claims are causing immediate and irreparable competitive and commercial injury to Sanofi US, to its goodwill and reputation, and will continue to cause such injury unless enjoined by this Court.

45. On information and belief, Defendant's acts of false advertising are willful, deliberate, and in bad faith.

46. Sanofi US has no adequate remedy at law.

47. Sanofi US is entitled to injunctive relief and to recover up to three times its actual damages under N.J. Stat. Ann. § 56:4-2.

COUNT III:
UNLAWFUL PRACTICES
N.J. STAT. ANN. § 56:8-1 *ET SEQ.*

48. Sanofi US repeats and incorporates by reference the allegations contained in the foregoing paragraphs 1-47 as if fully set forth herein.

49. The New Jersey Consumer Fraud Act ("NJCFA") prohibits as an unlawful practice:

> [t]he act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing, concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise . . . .
>
> N.J.S.A. § 56:8-2.

50. Defendant's commercial advertising and promotional claims described above constitute unconscionable commercial practices and misrepresentations in violation of the NJCFA as Defendant, upon information and belief, knowingly misrepresented the nature, characteristics, and qualities of Sanofi US's Lantus and Toujeo products to deceptively encourage a switch from those products to Defendant's drug, Tresiba.

51. Defendant's unlawful practices have caused Sanofi US ascertainable loss: the loss of Lantus and Toujeo customers.

52. Defendant's commercial advertising claims are causing immediate and irreparable competitive and commercial injury to Sanofi US, to its goodwill and reputation, and will continue to cause such injury unless enjoined by this Court.

53. On information and belief, Defendant's acts of false advertising are willful, deliberate, and in bad faith.

54. Sanofi US has no adequate remedy at law.

55. Sanofi US is entitled to recover up to three times its actual damages and/or an award of Defendant's profits, as well as costs, filing fees, and Sanofi US's reasonable attorney fees, under N.J.S.A. §§ 56:8-2.11, -2.11, -19.

COUNT IV:
COMMON LAW UNFAIR COMPETITION, UNFAIR SALES PRACTICES AND/OR DECEPTIVE SALES PRACTICES

56. Sanofi US repeats and incorporates by reference the allegations contained in the foregoing paragraphs 1-55 as if fully set forth herein.

57. The conduct described above and throughout this Complaint constitutes unfair competition, unfair sales practices, and deceptive trade practices under the common law of the State of New Jersey.

58. Defendant's commercial advertising and promotional claims described above are false and misleading statements of fact, that misrepresent the nature, characteristics, and qualities of Sanofi US's Lantus and Toujeo products, and that both deceive and have the capacity to deceive a substantial segment of relevant consumers and potential consumers for the parties' insulin products.

59. Defendant's deception and intended deception was and is material, in that it was and is likely to influence relevant consumers' purchasing decisions.

60. Defendant's commercial advertising claims have caused and are likely to continue to cause damage to Sanofi US and the public, and, unless restrained, will further damage Sanofi US and the public.

61. Defendant's commercial advertising claims are causing immediate and irreparable competitive and commercial injury to Sanofi US, to its goodwill and reputation, and will continue to cause such injury unless enjoined by this Court.

62. On information and belief, Defendant's acts of false advertising are willful, deliberate, and in bad faith.

63. Sanofi US has no adequate remedy at law.

64. Sanofi US is entitled to damages.

COUNT V:
COMMON LAW PRODUCT DISPARAGEMENT

65. Sanofi US repeats and incorporates by reference the allegations contained in the foregoing paragraphs 1-64 as if fully set forth herein.

66. The conduct described above and throughout this Complaint constitutes common law product disparagement.

67. Defendant published with malice false allegations about Sanofi US's Lantus and Toujeo products that caused special damages, including pecuniary harm.

68. Defendant's commercial advertising claims are causing immediate and irreparable competitive and commercial injury to Sanofi US, to its goodwill and reputation, and will continue to cause such injury unless enjoined by this Court.

69. On information and belief, Defendant's acts of false advertising are willful, deliberate, and in bad faith.

70. Sanofi US has no adequate remedy at law.

71. Sanofi US is entitled to damages.

PRAYER FOR RELIEF

WHEREFORE, Sanofi US demands judgment in its favor, as follows:

1. That Defendant, its parents, subsidiaries, affiliates, principals, employees, agents, officers, directors, shareholders, attorneys, representatives, successors, and assigns, and all persons in active concert and participation with them or any of them:

A. Be preliminarily and permanently enjoined from publishing or otherwise disseminating to relevant consumers and/or the public any false or misleading statements concerning Sanofi US's Lantus and Toujeo products, or otherwise engaging in false or misleading advertising concerning, or unfair competition with, those products;

B. Be ordered to recall and destroy all physical brochures, advertisements, press releases, and promotional materials that contain false or misleading statements concerning Sanofi US's Lantus and Toujeo products, including without limitation those set forth in Exhibits A-C hereto;

C. Be ordered to issue corrective advertising retracting its false and misleading statements concerning Sanofi US's Lantus and Toujeo products to all recipients of Defendant's advertising containing such statements, and by posting such retractions on its websites and social media account home pages for at least six (6) months.

2. That Defendant be directed to file with this Court and serve upon Sanofi US within thirty (30) days of entry of such judgment a report in writing and under oath setting forth in detail the manner and form in which Defendant has complied with the above.

3. That an accounting be ordered and that Sanofi US be granted the amount of Defendant's profits realized and/or of the actual and/or enhanced damages sustained by Sanofi US in consequence of Defendant's unlawful acts as found by the Court, together with such punitive and/or exemplary damages permitted by state law, and appropriate interest on such damages.

4. That Sanofi US be granted its costs and reasonable attorneys' fees.

5. That Sanofi US be granted any additional relief that this Court deems just and proper.

JURY TRIAL DEMAND

Sanofi US respectfully demands a jury trial pursuant to Rule 38(b) of the Federal Rules of Civil Procedure on all claims and issues so triable.

Dated: December 23, 2016

Respectfully Submitted,

s\ David B. Hennes

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